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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,062	04/30/2002	Thomas Moore	GK-OEH-120/500814.20021	7191

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REED SMITH, LLP  
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599 LEXINGTON AVENUE, 29TH FLOOR  
NEW YORK, NY 10022-7650

EXAMINER
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ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,062	<b>Applicant(s)</b> MOORE ET AL.	
	<b>Examiner</b> Marianne P. Allen	<b>Art Unit</b> 1631	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 pages</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-12 have been cancelled and claims 13-24 have been newly introduced.

The original abstract has been replaced with the abstract submitted 1/4/02.

#### ***Specification***

The substitute specification filed 1/4/02 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: The substitute specification was not accompanied by marked up copy indicating the changes made nor a declaration with respect to the substitute specification containing no new matter. Note that should applicant submit a new substitute specification, such a submission would need to comply with the new rules for amendment.

**Examination of the instant application has been with respect to the originally filed specification and not the substitute specification.**

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Several of the claim limitations set forth in claim 13 are not present in the specification. See at least for example, "subjecting the proteome to a number  $n$  of different separating processes for  $n > 2$ ." In addition, none of the limitations of claims 14-24 (corresponding to original claims 2-12) are disclosed in the specification. While the original claim numbers are mentioned on page 7, lines 24-25, the content of these claims do not appear to be disclosed in the specification.

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It is further noted that both the original and substitute abstracts recite “by o different analysis processes” whereas the claims and specification recite “by  $\tau$  different analysis processes.” Clarification is requested.

### ***Drawings***

It is noted that the description of the figures in the specification refer to subparts not present in the figures. (See page 8.) The numbering is inconsistent. Clarification and/or correction is requested.

### ***Claim Rejections - 35 USC § 112***

Claims 13-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 13-24 are not original claims and no basis has been pointed to in support of these new claims other than the originally filed claims. However, at least the limitation “determining said liquid ratio quantitatively” in claim 1 does not appear in original claim 1 nor does it appear to be present in the specification.

Should this new matter rejection be overcome, the claims would be subject to at least the following enablement rejection.

The specification provides no explanation, guidance, or examples as to how a liquid ratio is used to obtain an n-dimensional image of the proteome. The specification does not provide a

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clear explanation as to how the analysis data from the preceding steps is combined to obtain the n-dimensional image characterized by identifiers and quantifier and by position. For example, suppose  $n=4$ ,  $m_1=4$ ,  $m_2=6$ ,  $m_3=10$ ,  $m_4=2$ , and  $\tau = 5$ .  $M$  is  $4 * 6 * 10 * 2 = 480$ . How is the information from the 2400 ( $\tau * M$ ) identifications combined to produce the 4-dimensional image of the proteome, particularly when the number of proteins present in the proteome is unknown? How is the number of liquid fractions required or desirable for each step determined?

Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites “determining said liquid ratio quantitatively by known quantification processes.” There is no antecedent basis in the claim for “said liquid ratio” and the specification does not disclose this concept nor any known quantification processes for this ratio. As such, it cannot be determined what the claim is directed to.

Claim 13 recites “in a subsequent separating steps.” It appears that there is an error in this text.

Claim 14 recites “according to the affinity of the protein, with respect to specific ligands, also to antibodies are selected.” This phrase is confusing as to what was intended.

Claim 16 recites “selected as quantification methods.” It is unclear if this refers to the quantification in line 11 or line 12 (or both) of claim 13.

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Claim 19 recites "in the manner of and with the layout of microtitration plates." It is unclear what is meant by this phrase. In addition, it is unclear if this step occurs after each and every separation step or only particular ones.

Claims 20-21 recite "preferably in the n \* 96 grid of microtitration technology." It is unclear if this is a specific limitation of the claim.

Claim 23 recites "which are known per se." It is unclear how applicant intends this limitation to be interpreted.

Claim 24 recites "wherein the analysis data...are assembled in a database." It cannot be determined what specific pieces of information are required to be present in the database in order to meet the limitation of the claim. Does this mean only the final n-dimensional data space representation? Does it include the number of liquid fractions? Does it include identifiers and quantifiers?

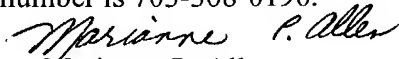
### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

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